DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 2 2000

John F. Bruni, Ph.D.
Director, Clinical and Regulatory Affairs
Biosite Diagnostics
11030 Roselle Street
San Diego, California 92121

Re: K000231
Trade Name: Triage® BNP Calibration Verification Controls
Regulatory Class: I
Product Code: JJX
Dated: January 21, 2000
Received: January 27, 2000

Dear Dr. Bruni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may not market this device, however, until such time as the premarket approval application, P990082 for the device Biosite BNP is approved by the Food and Drug Administration (FDA). When the device is marketed, it will be subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

However, you are responsible for determining if the medical devices you use as components in the Biosite BNP have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the Act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System (QS) Regulation for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification subject to approval of the Biosite BNP. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

S. Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number if known) K000231

Device Name: Triage® BNP (B-Type Natriuretic Peptide) Calibration Verification Controls

Indications for Use:

The Triage® (B-Type Natriuretic Peptide) Calibration Verification Controls are controls used to assess the daily performance of the Triage® BNP Test. These controls contain B-Type Natriuretic Peptide (BNP) at three concentrations.

Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000231

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE **ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The Counter Use___